IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION
No. 5:08-CV-00160-D

SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC,	)
Plaintiffs,	)
v.	)
SYNTHON HOLDING BV, SYNTHON BV, SYNTHON PHARMACEUTICALS, INC., and SYNTHON LABORATORIES, INC.,	)
Defendants.	)

STIPULATION, CONSENT JUDGMENT AND PERMANENT INJUNCTION

This Stipulation, Consent Judgment and Permanent Injunction ("Consent Judgment") is entered into by and between Plaintiffs, Sanofi-Aventis and Sanofi-Aventis U.S. LLC (collectively, "Plaintiffs"), and Defendants, Synthon Holding BV, Synthon BV, Synthon Pharmaceuticals, Inc., and Synthon Laboratories, Inc. (collectively, "Defendants"), subject to approval by the Court.

WHEREAS, Sanofi, a successor to Sanofi-Aventis and Sanofi-Aventis U.S. LLC, is the owner of United States Patent No. 6,514,531 ("the '531 Patent), entitled "Controlled-release dosage forms comprising zolpidem or a salt thereof," which issued on February 4, 2003;

WHEREAS, Synthon Laboratories, Inc. filed with the United States Food and Drug Administration ("FDA") Abbreviated New Drug Application ("ANDA") No. 78-483, seeking

approval for the manufacture, use and sale of generic zolpidem tartrate extended release tablets in 6.25 and 12.5 mg dosage strengths;

WHEREAS, Synthon Laboratories, Inc. provided Plaintiffs with notice that ANDA No. 78-483 contains a certification pursuant to 21 U.S.C. § 505(j)(2)(A)(vii)(IV) alleging that the claims of the '531 Patent are invalid or not infringed by Synthon Laboratories Inc.'s proposed generic zolpidem tartrate extended release tablets;

WHEREAS, Plaintiffs brought this action in the United States District Court for the Middle District of North Carolina against Defendants on February 5, 2007, charging Defendants with infringement of the '531 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A) and alleging that any commercial manufacture, use, offer for sale, sale and/or importation of the generic zolpidem tartrate extended release products for which Defendants were seeking approval in ANDA No. 78-483 would infringe one or more claims of the '531 Patent;

WHEREAS, by Order dated March 20, 2008, the case was transferred from the Middle District of North Carolina to this Court;

WHEREAS, on August 2, 2007, pursuant to 35 U.S.C. § 311, Synthon Laboratories, Inc. filed a request for *inter partes* reexamination of the '531 Patent with the United States Patent and Trademark Office ("USPTO"), which was granted on November 1, 2007 ("the '531 Reexamination");

WHEREAS, on May 22, 2008, Plaintiffs and Defendants (collectively, "the Parties") jointly moved this Court to stay this action pending a decision of the USPTO in the '531 Reexamination that has not or cannot be further appealed within the USPTO;

WHEREAS, on June 16, 2008, this Court entered a Stay Order granting a stay of this litigation as requested in the Parties' joint motion;

WHEREAS, on March 27, 2013, the Patent Trial and Appeal Board ("the Board") issued a decision in the '531 Reexamination reversing the USPTO Examiner's prior rejections of all of the claims of the '531 Patent;

WHEREAS, Synthon Laboratories, Inc. unilaterally, and without any input or consideration from Plaintiffs, decided not to request rehearing of the Board's decision or appeal the Board's decision to the United States Court of Appeals for the Federal Circuit;

WHEREAS, in light of the foregoing, Defendants wish to conclude this litigation without contesting infringement, validity, or enforceability of any claims of the '531 Patent in this proceeding.

Now the Parties, by their respective undersigned attorneys, hereby stipulate and consent to entry of judgment and an injunction in these actions as set forth herein, and it is therefore ORDERED, ADJUDGED AND DECREED as follows:

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over the Parties.

2. As used in this Consent Judgment, (i) the term "Defendants' ANDA Product" shall mean any drug product sold, offered for sale or distributed pursuant to Abbreviated New Drug Application No. 78-483; and (ii) the term "Affiliate" shall mean with respect to a Party, any Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such Party at any time during the

period for which the determination of affiliation is being made. For the purposes of this definition, "control" (including the terms "controlled by" and "under common control with") means the possession, directly or indirectly, of the power to direct or cause the direction of the management, policies or affairs of a person, whether through ownership of voting securities or general partnership or managing member interests, by contract or otherwise, including the ownership, directly or indirectly, of securities having the power to elect a majority of the board of directors or similar body governing the affairs of such person. Without limiting the generality of the foregoing, a person shall be deemed to control any other person in which it owns, directly or indirectly, a majority of the voting interests.

3. Defendants do not contest that they have not met their burden of proving that the '531 Patent is invalid or unenforceable.

4. In any other or future cause of action or litigation, Defendants shall not dispute that the '531 Patent is enforceable and valid.

5. For themselves and their Affiliates, Defendants do not contest that the manufacture, use, sale, offer to sell or importation of Defendants' ANDA Product in or into the United States would infringe at least one claim of the '531 Patent pursuant to 35 U.S.C. §§ 271(a), (b), (c), and (e)(2). Nothing in this Consent Judgment shall be construed to abrogate, limit or otherwise affect Defendants' rights under the so-called safe harbor of 35 U.S.C. § 271(e)(1).

6. Defendants, including any of their Affiliates, successors and assigns, are enjoined until June 1, 2020 from making, having made, using, selling, offering to sell or importing Defendants' ANDA Product in or into the United States.

7. Prior to or promptly after its submission to the Court, Defendants, Plaintiffs or both Parties may file with the U.S. Federal Trade Commission Bureau of Competition ("FTC") and the Antitrust Division of the U.S. Department of Justice ("DOJ") this STIPULATION, CONSENT JUDGMENT AND PERMANENT INJUNCTION and any notifications required to be filed pursuant to Title XI of the Medicare Prescription Drug Improvement and Modernization Act (Subtitle B - Federal Trade Commission Review) signed into law on December 8, 2003 and any other applicable law. If either the FTC or DOJ has objections to this STIPULATION, CONSENT JUDGMENT AND PERMANENT INJUNCTION, then the Parties shall promptly meet and, in good faith, shall endeavor to modify, if possible, its terms to overcome any such objections. In the event this STIPULATION, CONSENT JUDGMENT AND PERMANENT INJUNCTION is modified pursuant to this Paragraph, the parties shall promptly submit the modified form for the Court's approval and entry as a modified judgment and injunction. In the event that the parties cannot, after good faith efforts, agree on a modified form of this STIPULATION, CONSENT JUDGMENT AND PERMANENT INJUNCTION or in the event the Court does not approve such modified form, then this STIPULATION, CONSENT JUDGMENT AND PERMANENT INJUNCTION shall be null and void *ab initio* and to the extent already entered by the Court, shall be vacated.

8. Defendants have agreed that, in the event of a breach or violation by Defendants of the terms of this Consent Judgment, jurisdiction and venue for an action for a preliminary injunction against the breaching conduct exists in this Court, and Defendants hereby waive any and all defenses based on personal jurisdiction and venue.

9. Compliance with this Consent Judgment may be enforced by Plaintiffs and its successors in interest, or assigns.

10. This Court retains jurisdiction to enforce or supervise performance under this Consent Judgment.

11. The above action, including all claims, counterclaims, affirmative defenses, and demands are hereby dismissed with prejudice and with each party to bear its own costs, disbursements and attorneys' fees.

This the 1 day of October, 2013.

JAMES C. DEVER, III
United States District Judge

We hereby consent to the form and entry of this Order.

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